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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,709	04/09/2004	Alexandre Huboux	81455-5730	8745
28765	7590	11/19/2004	EXAMINER	
WINSTON & STRAWN PATENT DEPARTMENT 1400 L STREET, N.W. WASHINGTON, DC 20005-3502			REYES, HECTOR M	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 11/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/820,709

Applicant(s)

HUBOUX, ALEXANDRE

Examiner

Hector M Reyes

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 3-6 is/are objected to.
- 8) ☒ Claim(s) 2,7,8-12 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/4/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of The Claims

Claims 1-12 are currently under Examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 2, 7, 8, 10, 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 while directed to define a process is ambiguous and indefinite since it is not clear what are the steps defining the claimed process. For example, the phrase "the treatment of" is indefinite because it is unclear what are the particular or the actual steps require in order to carried out the process. How the said treatment is carried out? Would it be enough to contact the racemate or its salt with the chiral auxiliary or it salt?

Similarly, regarding a solvent that is said to be required, the phrase " a solvent wherein the compounds of formula I or I' have different solubilities" lacks clarity because it is uncertain which solvents are indeed embraced by the said phrase. What solvent or solvents are required for a successful preparation and simultaneously are embraced under the phrase " a solvent wherein the compounds of formula I and formula I' have different solubilities? Would it be necessary to dissolve the said substances **before** or **after** combining each other? Is it necessary to increase the temperature once the

Art Unit: 1625

racemate and the enantiomer are combined? Is it necessary to cool the obtained mixture? if so, what are the temperature ranges in each steps of the process? Is a diastereoisomer pair obtained from the process? How the diastereoisomeric salts are separated in order to "obtained a compound of formula I or a compound of formula I'?" Adding more confusion yet and regarding the acid required in the preparation of the enantiomer salt, the phrase "with an acid having a pKa below 5" is indefinite, since there is no clear definition of what kind of acids are indeed intended to be embraced in the said phrase. Would an organic carboxylic acid having a pKa below 5 and a molecular weight excessively high satisfy this claim limitation even if it affects the solubility of the medium?

Claim 7 is indefinite and vague since while recites the limitation "A process for optical resolution of a compound....which comprises treating the compound with an optically active enantiomer ..." there is no steps defining the claimed process. An optical resolution is known in the art as being a very discreet process wherein each steps depend on the next in order to achieve the objective. Indeed factors such as solvent nature, temperature-ranges including heating and cooling and even the separation technique used to separate the diastereoisomers formed are essential but missing from the said claim.

Claim 8 is ambiguous and confusing since it recites the limitation:

Art Unit: 1625



8. A process according to claim 7, wherein the optically active enantiomer is obtainable by the reaction of an optically active enantiomer of 2-(methylamino)-1-phenyl-1-propanol with an acid having a pK_a below 5.

However, what is obtained after reaction with the acid is not the optically active enantiomer if not the corresponding ammonium salt thereof. How the "optically active enantiomer can be obtained after the reaction with the said acid?

Claim 9 is indefinite because it is unclear how the lactonization of the compounds I and I' is achieved in order to produce the allegedly enantiomers of sclareolide. What is the particular step wherein the lactonization is achieved? See MPEP § 2172.01.

Claim 10 is indefinite since it recites the limitation:

10. A process for obtaining (+)-sclareolide or (-)-sclareolide which comprises hydrolyzing (\pm)-sclareolide into a corresponding [(1RS,2RS,4aSR,8aSR)-2-hydroxy-2,5,5,8a-tetramethyldecahydronaphthalen-1-yl]acetic acid or a salt thereof.



However, the said claim lacks essential elements since it is well known in the art that a racemate resolution cannot be achieved by only hydrolyzing a racemate or its salt.

Thus the claim is considered as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are among others, the required the optically active enantiomer used as chiral auxiliary, the nature of the solvent used in the resolution, reaction conditions as

Art Unit: 1625

temperature range and particular mixing sequence and the method use to separate the expected diastereoisomers.

Claim 11 recites the limitation:

11. A process for obtaining (+)-sclareolide or (-)-sclareolide which comprises a process according to claim 2.

Thus, the said claim is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step(s) is (are) should described the way that (-) and (+) sclareolide are obtained from each of the salts allegedly obtained in the process described in claim 2.

Claim 12 is a reach through claim and thus is considered improper and is hereby rejected, since the phrase "under conditions that favor the optical resolution of the (+) or (-) sclareolide" reach through no even discovered conditions presently that would indeed be embraced under the said phrase. Moreover, the claim is incomplete because it omits essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step(s) is (are) should described the way that (-) and (+) sclareolide are obtained from the compounds of formula I or I'. How the said compounds are converted to the targets? When the said compounds would be starting materials? When they are required to be intermediates? What are the reactants and reaction conditions require for the said process?

Claims Objections

Claims 3-6 are objected because the said claims depend, directly or indirectly on rejected claims.

Allowable Subject Matter

No prior art disclosing or suggesting the salts described in claim 1 or its process of preparation via a resolution from the corresponding racemate and wherein an optically active enantiomer of (2-hydroxy-1-methyl-2-phenylethyl)methyl or a salts thereof is used as chiral auxiliary was found in the prior art of record. The closest art, relevant to Applicant's salts and or process was found in Asanuma et al, US patents 5290955 and 5347048. Asunuma discloses carboxylate salts as those described in claim 1 and its resolution, wherein the anion is a 1-(aryl)ethylamine, such as naphthylethyl amine derivatives. Asunuma's patents however, does not teach or suggest salts of optically active enantiomers of (2-hydroxy-1-methyl-2-phenylethyl)methyl and the said carboxylates or the resolution of the said carboxylates using the (2-hydroxy-1-methyl-2-phenylethyl)methyl or salts thereof.

CONCLUSION

Any inquiry concerning this communication should be directed to Hector M. Reyes whose telephone number is (571) 272-0691. The examiner can normally be reached on Monday to Friday from 9 am to 5pm.

Application/Control Number: 10/820,709

Page 7

Art Unit: 1625

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor Ms. Rita Desai, whose telephone number is (571) 272-0584 or Examiner's Supervisor Ms. Cecilia Tsang, at (571) 272-0562.

Héctor M. Reyes PhD, JD
Art Unit 1625
USPTO Reg. # 54846
November 17, 2004.

RDesai
11/18/04